

Appl. No. 10/750,428
Amdt. Dated October 12, 2004
Reply to Office Action of July 13, 2004

REMARKS/ARGUMENTS:

Claims 2, 9, and 13 are amended. Claims 1-28 are pending in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Claim Rejection Under 35 U.S.C. 112:

Claims 13 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Examiner states that "the connecting device" in claim 13 lacks antecedent basis. In response, the Applicants changed "the connecting device" to --the bubble-forming device--, which has its antecedent basis in claim 1, from which claim 13 ultimately depends. Withdrawal of this rejection is thus respectfully requested.

The Examiner states that "the lumen" in claim 9 lacks antecedent basis. In response, the Applicants changed "the lumen" to --the conduit--, which has its antecedent basis in claim 1, from which claim 9 depends. Withdrawal of this rejection is thus respectfully requested.

The Examiner states that "elevation" in claim 2 should be changed to --evaluation--. In response, the Applicants corrected this typographical error in the manner suggested by the Examiner.

Claim Rejection Under 35 U.S.C. 103:

Claims 1-5, 8, 9, 11-15, and 17-28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over either Gilcher et al. or Natwick et al., and further in view of Kline-Schoder et al. The Applicants respectfully traverse this rejection.

Claim 1 is as follows:

A system for evaluating or calibrating a bubble detector, comprising:
a conduit adapted to pass a flow material therethrough;
a pump operatively coupled to the conduit to pump the flow material through
the conduit;

Appl. No. 10/750,428
Amdt. Dated October 12, 2004
Reply to Office Action of July 13, 2004

a bubble-forming device operatively coupled to the conduit, the bubble-forming device being adapted to introduce bubbles into the flow material passing through the conduit; and

a bubble detector to be evaluated positioned to examine the bubbles in the flow material passing through the conduit.

Applicants respectfully submit that Gilcher, Natwick, and Kline-Schoder cannot render claim 1 obvious because the cited references fail to teach or suggest a system that has both a bubble-forming device and a bubble detector to be evaluated positioned to examine the bubbles in the flow material passing through the conduit.

According to the Examiner, Gilcher and Natwick teach that bubble detectors may be calibrated to respond to a particular size but neither reference gives any particulars. The Examiner further states that it would have been obvious to employ Kline-Schoder's system of Figure 13 to provide a calibration reference for either Gilcher or Natwick because Kline-Schoder teaches that a system employing conduit 12, peristaltic pump 118, and bubble forming device will produce bubbles having a particular size and number for testing. The Applicants respectfully disagree.

The fact that Gilcher and Natwick state that bubble detectors may be calibrated to respond to a particular size provides no motivation for combining either Gilcher or Natwick with Kline-Schoder. Furthermore, even if these references were combined, the combination would not result in the present invention.

The present invention offers the advantage that the bubble-forming device and bubble detector are positioned so that they can use the same flow materials. Flow materials of varying viscosity may be utilized and may include Newtonian or non-Newtonian fluids. It is the discovery of the present invention that the flow material to be evaluated be comparable with the viscosity of the material utilized in the operational environment, e.g., blood mixed with gas-enriched physiologic fluid. (Applicants' specification, at page 68, lines 6-18). On the other hand, as noted by the Examiner, a "glass tube" and a "water jet" are used in Kline-Schoder to produce bubbles. Thus, Kline-Schoder is limited to a water environment. Therefore, even if Kline-Schoder had a bubble detector, the simulation of operational

Appl. No. 10/750,428
Amdt. Dated October 12, 2004
Reply to Office Action of July 13, 2004

environments made possible with the present invention would still not be able to occur, since Kline-Schoder lacks the flexibility to accommodate different flow materials.

In summary, the Applicants respectfully submit that there is no motivation to combine or modify the cited references absent impermissible hindsight reasoning gleaned from the present application, and that there is nothing in the cited references that suggests the desirability of such a combination. Therefore, a prima facie case of obviousness has not been established. Furthermore, even if the cited references were combined, the combination would not result in the present invention.

In light of the foregoing, Applicants respectfully submit that the cited references cannot make claim 1 obvious, because the combination of references fails to teach or suggest each and every claim limitation.

Claims 2-5, 8, 9, and 11-13 depend from claim 1 and cannot be made obvious for at least the same reasons as claim 1. Withdrawal of this rejection is thus respectfully requested.

Claim 14 is as follows:

A method of evaluating or calibrating a bubble detector comprising the acts of:

- (a) pumping a flow material through a conduit;
- (b) introducing bubbles into the flow material;
- (c) examining the bubbles in the flow material with a bubble detector under evaluation; and
- (d) detecting the bubbles in the flow material.

Applicants respectfully submit that Gilcher, Natwick, and Kline-Schoder cannot render claim 14 obvious because the cited references fail to teach or suggest a method that both introduces bubbles into flow material and examines the bubbles in the flow material with a bubble detector under evaluation.

As discussed above, Gilcher and Natwick merely mention that bubble detectors may be calibrated to respond to a particular size without giving any specifics as to how this could be accomplished. In addition, also as discussed above, no motivation for combining either Gilcher or Natwick with Kline-Schoder is provided. Lastly, even if these references were combined, the combination would not result in the present invention.

Appl. No. 10/750,428
Amdt. Dated October 12, 2004
Reply to Office Action of July 13, 2004

In light of the foregoing, Applicants respectfully submit that the cited references cannot make claim 14 obvious, because the combination of references fails to teach or suggest each and every claim limitation.

Claims 15 and 17-28 depend from claim 14 and cannot be made obvious for at least the same reasons as claim 14. Withdrawal of this rejection is thus respectfully requested.

Claims 6, 7, 10, and 16 are objected to as being dependent upon a rejected base claim but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. The Applicants respectfully submit that since each of these claims depends from a claim that is believed to be patentable, claims 6, 7, 10, and 16 are believed to be patentable in their current form. Withdrawal of these objections is thus respectfully requested.

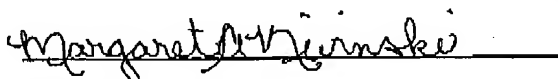
In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned attorney at the telephone number below to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1769, Order No. PA094-US.

Respectfully submitted,

Date: October 13, 2004


Margaret A. Kivinski
Reg. No. 38,517
TherOx, Inc.
2400 Michelson Drive
Irvine, California 92612
(949) 757-1999